FLOWCARDIA, INC.

510(k) Summary of Safety and Effectiveness

K051062

JUL 15 2005

Application Date:	**April 25, 2005**
Submission Type:	**510(k), Traditional**
Applicant Manufacturing Address:	**FlowCardia, Inc. (Owner)** **745 N. Pastoria Avenue** **Sunnyvale, CA 94085** **Ph: (408) 617-0352, Fx: (408) 617-9198** **Contact person: Richard Spano**
Establishment Registration:	**3005007189** **(Same as above)**
Device Common Name:	**Guidewire**
Device Trade Name:	**VP Wire GW140ST (.014" 165cm, Standard)** **VP Wire GW140SO (.014" 165cm, Soft)** **VP Wire GW143ST (.014" 300cm, Standard)** **VP Wire GW143SO (.014" 300cm, Soft)**
Device Classification:	**Class II (21CFR 870.1330), CDRH Code DQX,** **Cardiovascular Panel**
Reason for 510(k):	**New Device Submission**
Substantially equivalent to:	**K022762 (original), K031277 (special), K032615** **(special) Asahi Wire, product code: DQX** **K990639 CROSS IT 300XT, product code: DQX**
Contact Sterilizer:	**Nutek Corporation (Reg. No. 2950103)** **30958 San Antonio St** **Hayward, CA 94544**
Special Controls:	**No applicable mandatory performance standards or special controls exist for this device.**

Device Description

The FlowCardia VP Wire is a steerable guide wire with an outer diameter of 0.014" and available in 165 cm or 300 cm overall length. They are constructed from a stainless steel core wire with varying core and coil lengths for each design. The proximal end of the core wire is coated with polytetrfluoroethylene (PTFE). A short radiopaque coil tip is soldered to the distal end of the core wire.

Intended Use

The VP Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

Technological Characteristics as Compared to Predicate Device:

The FlowCardia VP Wires are constructed from the same materials, offered in the same lengths and diameters, have the same designs and indications for use as the predicate devices and other PTCA Guide Wires that are currently on the market.

Performance Data:

Animal, Bench, and Biocompatibility testing was conducted according to the relevant guidance documents to demonstrate that the FlowCardia VP Guide Wires met the acceptance criteria and performed similarly to the predicate devices. The following functional tests were performed: Tensile Strength, Torque Strength, Torqueability, Tip Flexibility, Coating Adherence/integrity, Biocompatibility, and Catheter Compatibility. No new safety or effectiveness issues were raised during the testing.

Conclusion:

The FlowCardia VP Guide Wires are substantially equivalent to the claimed predicates devices and other currently marketed PTCA Guide Wires.

Premarket Notification [510(k)] Number

745 North Pastoria Avenue, Sunnyvale, CA 94085-2918
Phone: (408) 617-0352 Fax (408) 617-9198

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 5 2005

Flowcardia, Inc.
c/o Mr. Richard Spano
Vice President, Operations and Quality
745 North Pastoria Avenue
Sunnyvale, CA 94085-2918

Re: K051062
Trade/Device Name: FlowCardia VP Wires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 25, 2005
Received: May 3, 2005

Dear Mr. Spano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vrchmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K051062

Device Name: **FlowCardia VP Wires**

Indications for Use:

The VP Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

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